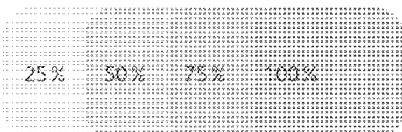


pure, mild & gentle colors

Pure, Mild & Gentle:



JOHNSON'S® lotion pink
pantone 1895
c=0 m=27 y=7 k=0



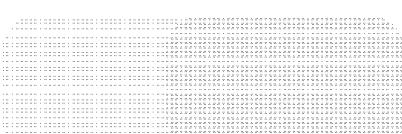
JOHNSON'S® natural green
pantone 366
c=20 m=0 y=44 k=0



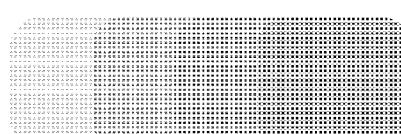
JOHNSON'S® gold shampoo
pantone 135
c=0 m=19 y=60 k=0



JOHNSON'S® baby bath blue
pantone 2975
c=30 m=0 y=5 k=0

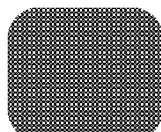


JOHNSON'S® HEAD-TO-TOE® yellow
pantone 100
c=0 m=0 y=51 k=0

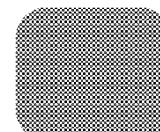


JOHNSON'S® bedtime lavender
pantone 2635
c=28 m=27 y=0 k=0

Typography & Icons:



JOHNSON'S® blue
pantone 300
c=100 m=44 y=0 k=0



JOHNSON'S® icons
(for NMT & CPM use)
pantone 191
c=0 m=76 y=38 k=0

pure, mild & gentle typography

To keep the look simple and aspirational, never deviate from or use more than these two typefaces per page.

Headline Copy: Bauer Bodoni Bold

Body Copy: FS Albert Regular

Body copy should never be in black but a dark color related to your color palette. Never use hyphenated words in your copy. Make your copy inviting by increasing the size if necessary.

Keep copy to a minimum.

Secondary Fonts: Only when the fonts specified above are not available (ppt presentations, etc.).

Headline Copy: Georgia Bold

Body Copy: Arial Regular

Headline set in
Sauer Bodoni Bold
lowercase preferred

- All body copy set in
FS Albert Regular

pure, mild & gentle
voice

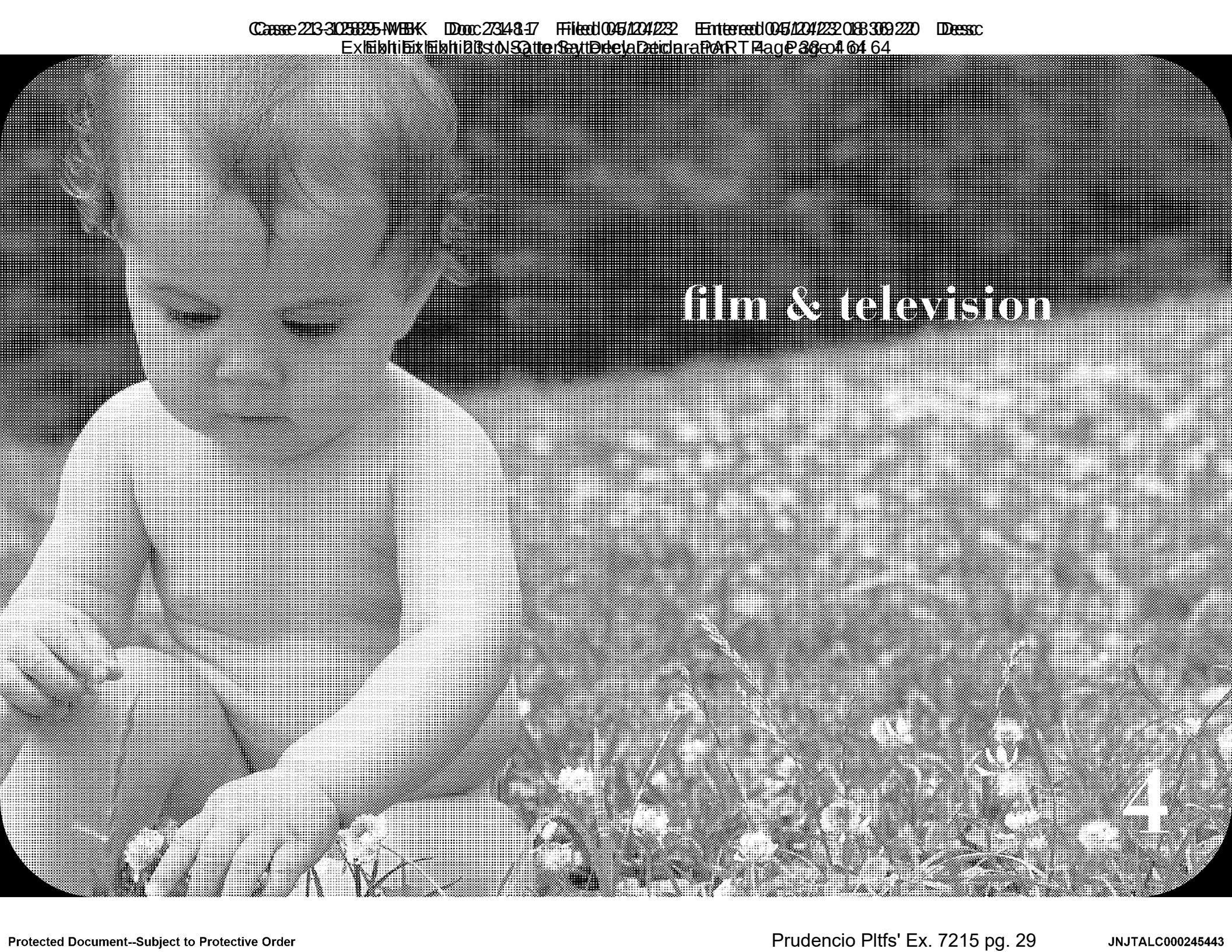
The "voice" that is JOHNSON'S® must touch you emotionally, yet satisfy rationally. It is caring, thoughtful, warm and reassuring. Our voice is not silly, frivolous, preachy or syrupy sweet.

The language mirrors the way mothers talk about their babies. It is real and everyday, simple and straightforward, not complicated or haughty.

We should never sound like a sales person, manufacturer or retailer. Use words that would be relevant in a baby's world; soft, carefully chosen words, not noisy, pushy, or self-important ones.

We come from a scientifically grounded, sensible, caring place. Still, our voice is not without a sense of humor and a smile, as we, like babies, are joyful.





film & television

4

the moment within a moment

We must always try to capture what we call the "moment within a moment."

Since our products live in the intimate space between a mother and child, we dramatize that space. We magnify the mom/baby bond by showing it up close, dramatically slowing it down and allowing it to play out naturally, always emphasizing the baby.

We show the moment where the JOHNSON'S® product comes into play and makes a difference: a caress, a touch, a connection, enhanced by the lotion, bath, wash or shampoo etc.

We should linger on the baby a bit longer than the viewer expects, to really allow baby's natural reactions to mom and to JOHNSON'S® baby product.

43



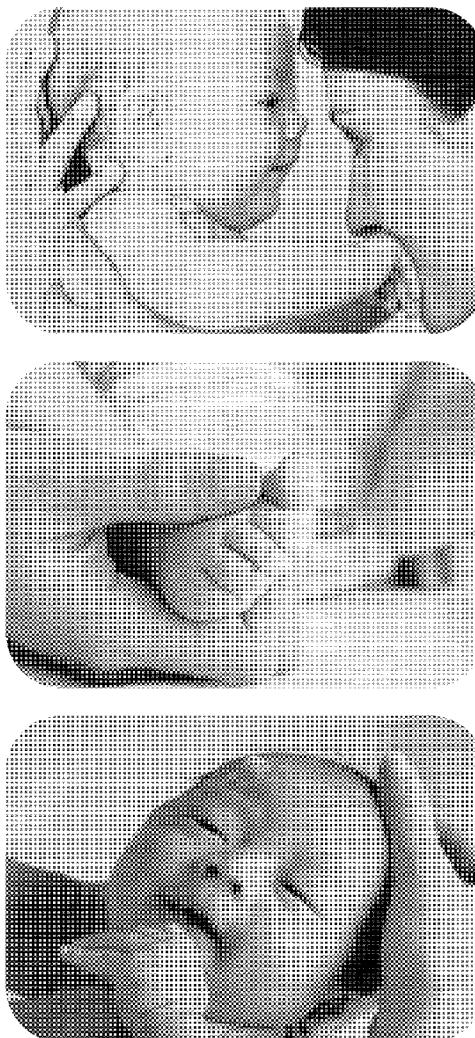
framing

The emphasis of the framing throughout the film should be 80 % baby 20 % mom. We should feel like we are a part of the intimate moment. We capture nuances of baby's reactions to mom. It is often effective to shoot over the mother's shoulder or show just a bit of her face. Close ups of little fingers and toes, and tiny movements that baby makes like facial reactions, smiles or reaching, are key.

The objective is always to show the unique magic and emotions of the mom-baby bond, and how JOHNSON'S® adds to that.

At some point we do want to see a close-up on a beautiful baby face nearly filling the screen. This is how moms see their baby, and it is appealing to any viewer. Remember, babies eyes speak volumes, and can communicate about our products well, i.e. they are gentle to eyes, calming or comforting.

4.2



music, sound & announcer

While not always required, music should always be beautiful, optimistic and enhance the JOHNSON'S® equity of pure, mild and gentle.

It is also helpful to layer in natural sound effects of babies, even over the music. Tiny gurgles and breaths are part of what make babies so appealing. But it must sound natural, not like the generic baby giggles used so artlessly in many other baby films on air today.

The voice of the announcer, when used, can be male or female, but should be warm, caring, sympathetic and knowledgeable. It can be effective to ask the announcer to speak very softly, and deliver their performance as if speaking around a sleeping baby, but this of course, depends on the message and drama.

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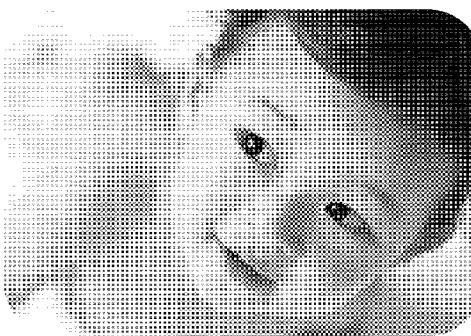
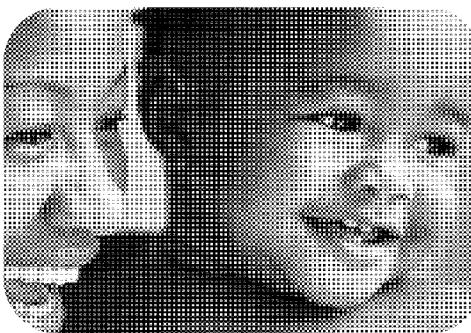


casting

JOHNSON'S® casting is critically important. JOHNSON'S® babies are especially beautiful, healthy, and happy; not too slim, not too plump. Their skin is smooth and unblemished. Lovely big eyes, soft, shiny hair, nicely proportioned features and sweet dispositions define the JOHNSON'S® baby. Young babies reinforce the "gentle" communication, yet we must always be age appropriate to the products.

When possible, casting real mothers with their babies can yield genuine magic. At the very least, actresses who play the mother should be very good around babies and at ease around them. Mothers, fathers, siblings and grandparents, when used, should be attractive and attentive to the baby's needs.

4.4



set & props

The JOHNSON'S® family lives in a slightly aspirational world, in a clean, nicely decorated and very loving home. The set or home should reflect this. All props should be beautiful and in the JOHNSON'S® palette. Whenever possible, soft, gentle, smooth and rounded props will add to the overall "pure, mild and gentle" mood.

4.5

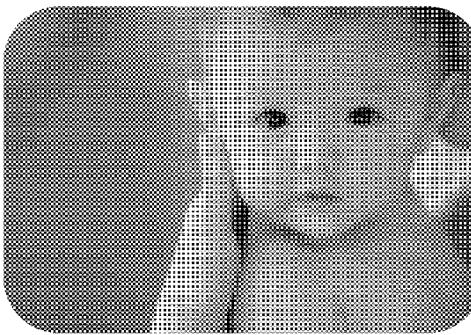


lighting & look of film

The lighting should appear clean, soft and natural. It can be clear and crisp, or soft and very slightly diffused, but should always look clean and pure, never dark or moody. Shooting outside or near a window with natural light is always a great idea to make the baby and mom look beautiful. Just be careful of harsh, bright light and shadows. When shooting shiny baby hair, golden sunlight, especially diffused sun in the late afternoon or early morning, is ideal.

When going to finish film, the skin must look beautiful, on baby and on mom, so the color correct should done with this in mind.

4.6



signature shots NO MORE TEARS®

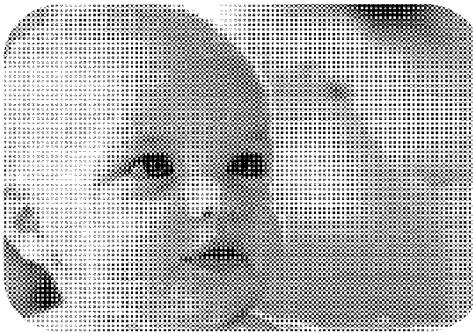
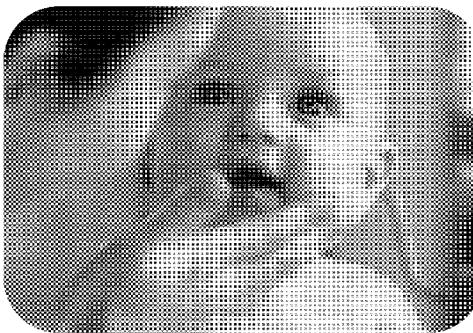
JOHNSON'S® baby was the first to introduce this level of reassurance, 50 years ago. We should always make it a point in the TVC when a product contains NO MORE TEARS®.

We should see soap suds moving dramatically towards and over the baby's eyes, and then feel the relief as it doesn't sting them. This can be further enhanced by the baby laughing and smiling.

The terminology describing it should be consistent "as gentle to the eyes as pure water".

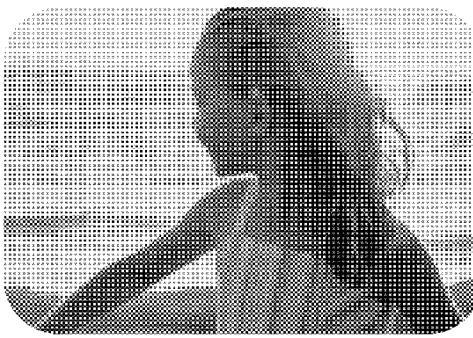
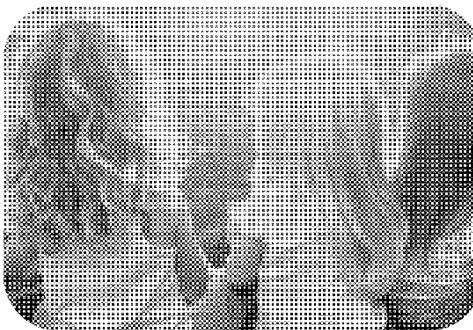
We can show the NO MORE TEARS® logo or clinically proven mild, or 90 % pediatrician recommended or pure, mild, gentle, on screen at the relevant time.

4.7



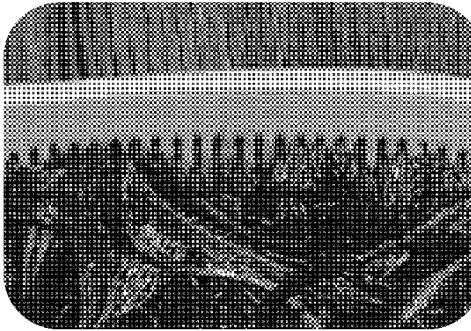
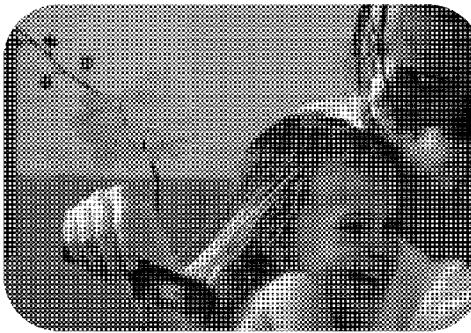
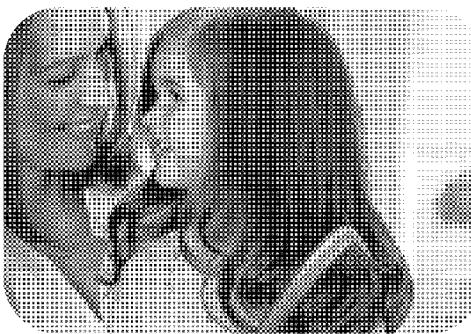
signature shots sunlit curls

Baby hair is the gold standard for shiny, silky, healthy hair. JOHNSON'S® baby simply highlights all that perfection. Show hair, whenever possible, in sunlight, and always beautifully lit. Soft, bouncy curls, captured in slow motion, are ideal. Shiny, silky straight hair, with all its reflections, is also beautiful, and looks especially good when moving.



signature shots shampoo comb thru

A comb thru is a moment of truth for parents and children. A tangle can lead to struggles and tears. A smooth, tangle free comb thru in itself is a relief, and can contribute to a delightful, enjoyable moment for all. Be sure and shoot this fairly close up to maximize for drama of going from tangled hair, to smooth, silky hair with one stroke.



signature shots bedtime

It is wonderful to shoot sleepy babies close, capturing tiny movements like fluttering eyes or twitching fingers as they sleep.

Safety guidelines should always be followed: For example, babies should sleep on their backs, in most cultures, to avoid SIDS (Sudden Infant Death Syndrome).

4.10



signature shots soft skin

Baby skin is the gold standard.

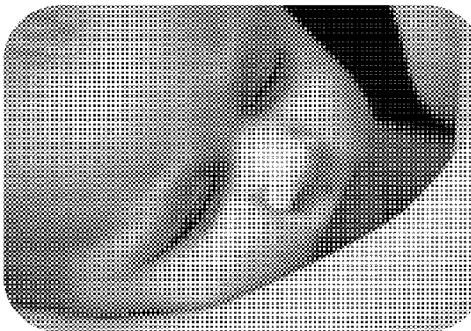
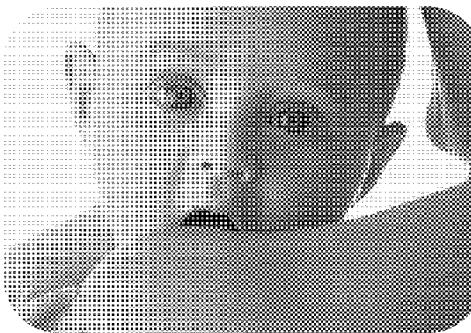
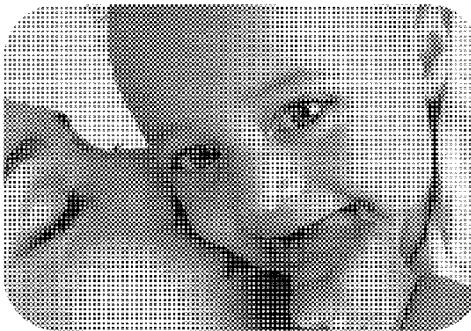
The baby's skin should look soft, smooth, glowing, flawless, healthy and cushiony.

Perfect baby skin looks, feels and smells great. We should include as many sensory cues as possible.

To further highlight the benefits of our products on skin, we might wish to show a "skin moment."

Using cool or neutral colors as backgrounds allows the skin to stand out and glow.

4.11



role of the baby

The baby in any communication should be more than a prop. He should be an integral part of the overall story.

The baby cast will be at an age relevant to the message or product, but usually under 18 months old.

The baby will never use the product on himself without a mom, or present the product to the viewer.

The baby should behave naturally, and not be manipulated, animated or made to act in an unnatural manner.

4.12



role of the mother

The JOHNSON'S® baby mother loves being a mom, and we will always celebrate the joy of motherhood in a positive way.

The JOHNSON'S® baby mother would never do anything unkind, or tease her baby – even as a joke.

The mother is a responsible mom. The well-being and safety of her baby come first, and she is in no way selfish about that.

She would never reject the baby in any shape or form.

If the idea demands it, a father, sibling or grandparent may be present in the commercial as well. However, the key relationship JOHNSON'S® portrays is the mother-baby relationship.

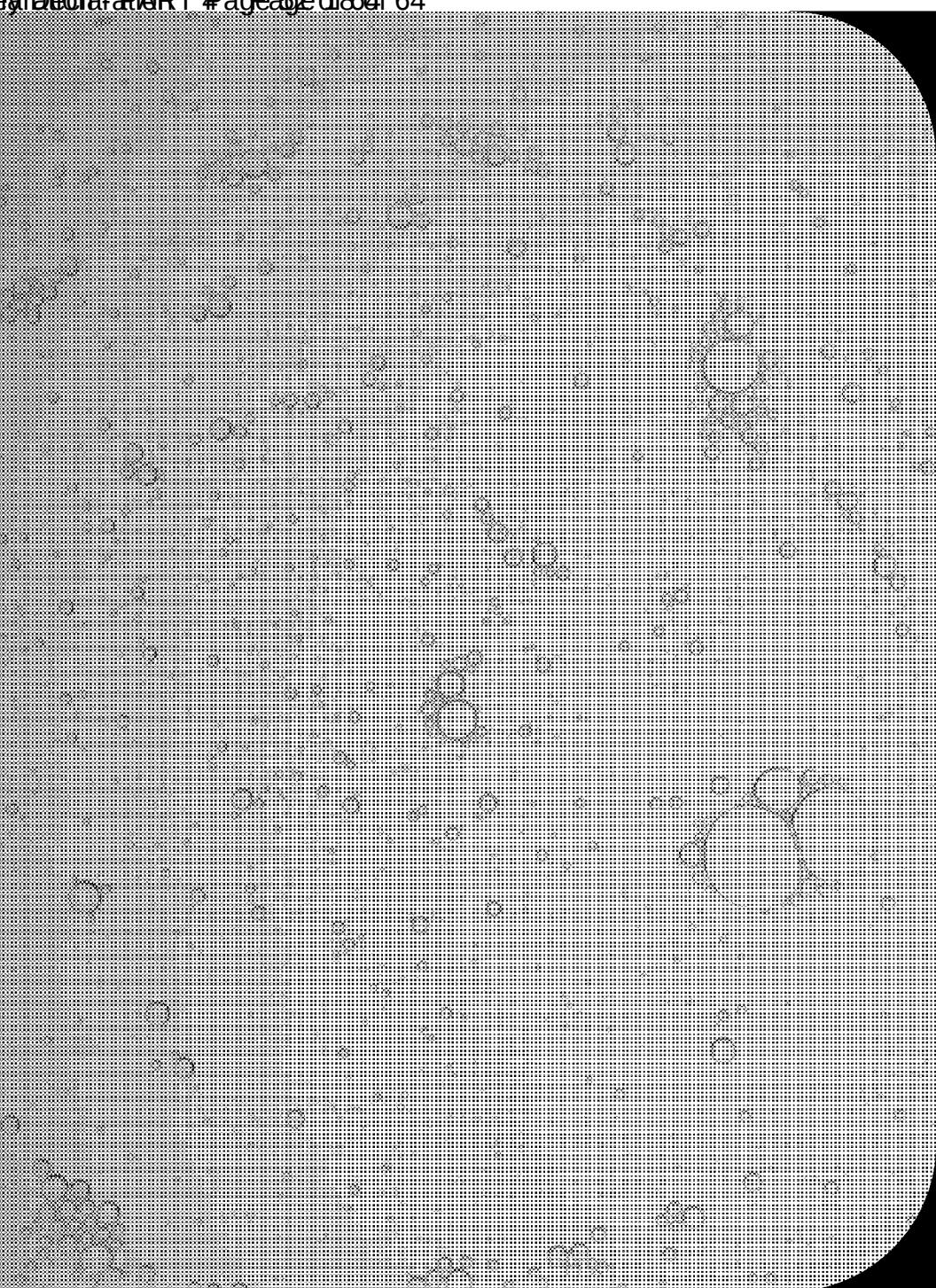


role of the product

We should see our products in our ads (the cream, the lather, the powder etc, as opposed to just the pack shot), and they should look beautiful.

We should highlight the sensory nature of our products: creamy textures, smell, etc.

Some ways to showcase our products could be through pouring shots, demo shots, application to skin shots.



application shots

The mother should apply the product on the baby. The baby will never apply the product on himself/herself without a parent being present. The baby can join in the application of product together with mom, when appropriate and natural.

The application moment should be either tender and intimate, or playful and fun, and let us see plenty of beautiful skin, and enjoyment while using the product.

4.15



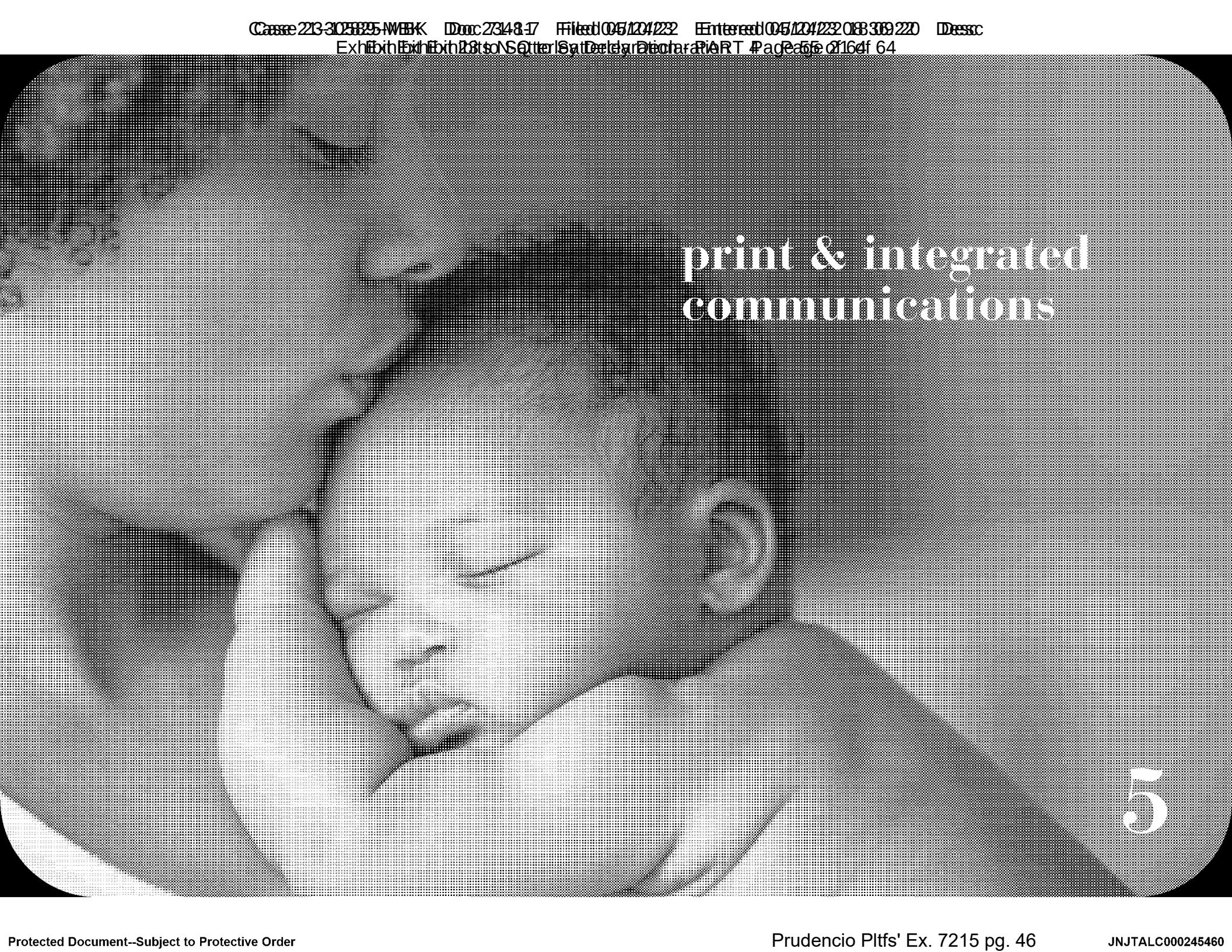
best for baby best for you

It is no secret that many women, even those without babies, love using JOHNSON'S® Baby products on themselves. This is a behavior that we encourage. We should let them associate the lovely attributes of baby skin, that it is perfectly soft, smooth, with a delicate, unmistakable scent, with those same attributes of our baby products.

In our communication, we should show babies in all their glory, but the main message should be to show women what our baby products can do to make them feel soft, beautiful and cared for, as only JOHNSON'S® can do.

4.16





print & integrated
communications

5

print

JOHNSON'S® print should always communicate our pure, mild & gentle attributes. The elements of look, feel and tone, palette, voice and casting that apply to film, apply to print as well.

While a JOHNSON'S® print layout is not strictly dictated, it should center on a 4-color, full-bleed photograph (see section on photography format). The headline should be readable and in the approved Bauer Bodoni typeface. The body copy should be as short and clear as possible, set in FS Albert Regular. Copy should never be in black.



headlines

Headlines should deliver the functional attributes of the brand in a clear and simple way, while also maintaining the unique voice of JOHNSON'S®.

For example:

"Other suds may look the same, but her eyes will feel the difference."

"Now the gentlest baths are also the bubbliest."

5.2



photography

The real key to a JOHNSON'S® baby ad is state of the art photography. Whether mom is in the shot, a beautiful JOHNSON'S® baby should dominate the photograph always with some note of the parent's presence. A good guideline is 80 % baby, 20 % mother. Preferably The picture should be full-bleed. Make sure that the color palette is our JOHNSON'S® palette, and that colors in the photo emphasize the color of the featured product.

Recommended photographers:

North America

Frank Heckers, Big Leo Productions: www.frankheckers.com
mail@frankheckers.com 212-625-3861

Latin America

Mauricio Nahas: www.mauricilonahas.com.br
Contact Fernando Machado: fms@terra.com.br +5511-5505-6900

Ricardo Barcelos:

Contact Fernando Machado: fms@terra.com.br +5511-5505-6900

Telma Vilas Boas: www.thelnavillasboas.fot.br

Contact Brisa: fms@terra.com.br +5511-2558-9161

Dan Escobar: www.danescobar.com

Contact Dan / Laura: dan@danescobar.com 415-777-0916

Asia Pacific

Scott Woodward: www.scottawoodward.com
scott@scottawoodward.com +65-9336-3526

EAME

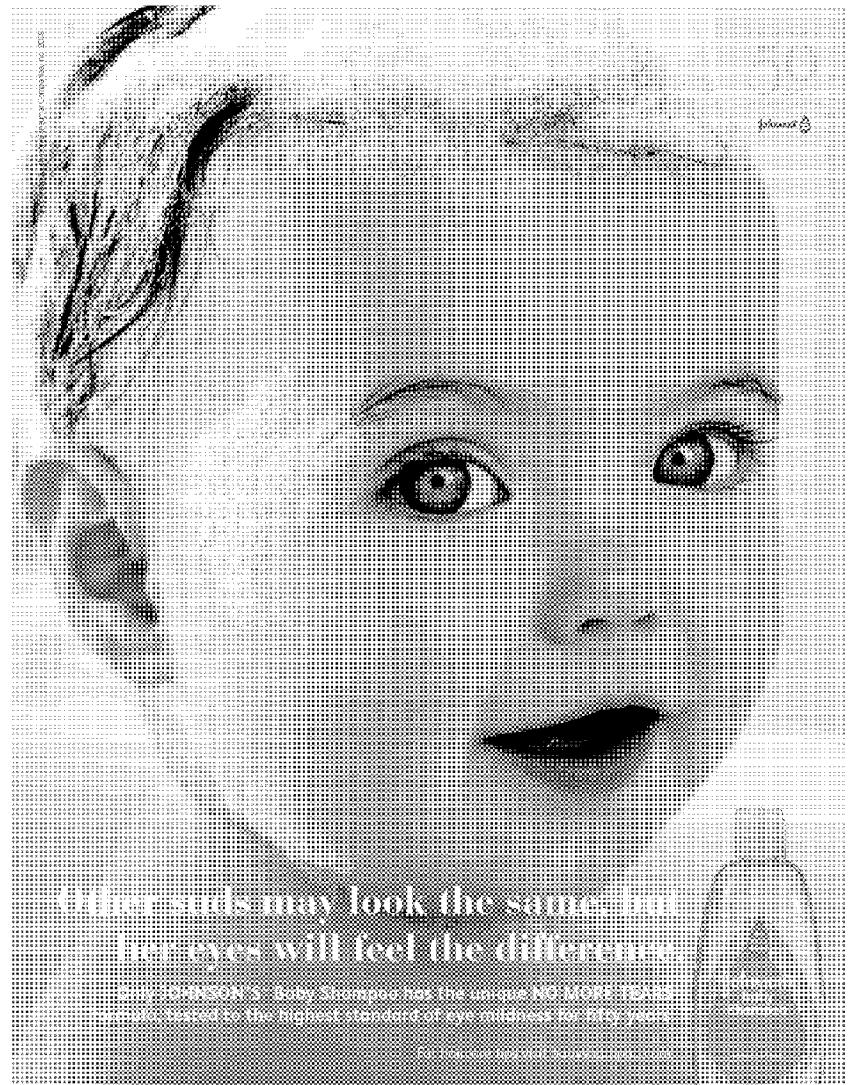
Gemma Booth: www.santucciandco.com, +44 (0)20 7226 7705

product shots

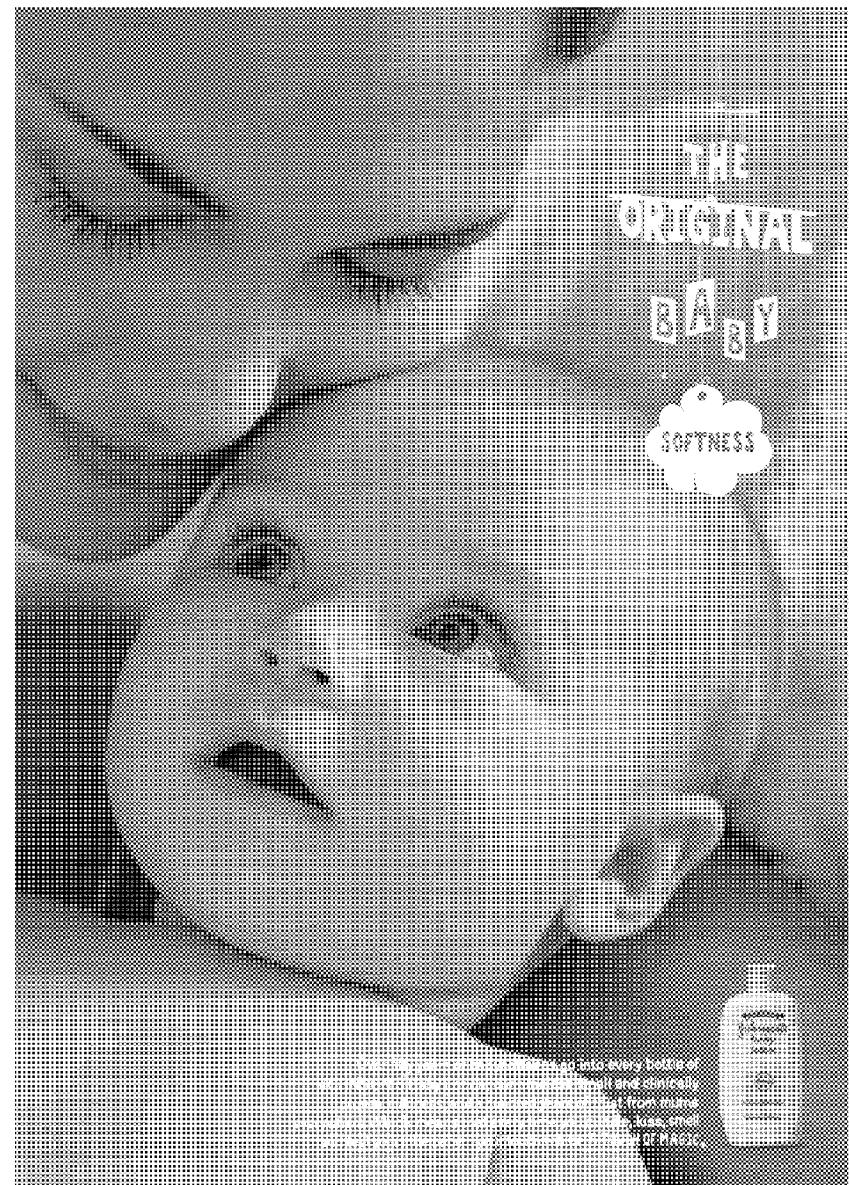
Products often look best shot in-situation, as long as it looks beautiful and clear. While the products do not need to be over-sized or heroic, they should be shot with respect, warmth and authenticity.



US layout



UK layout



AP layout

COMING SOON

LA layout

COMING SOON



Exhibit R

Johnson & Johnson

New Brunswick, N. J.
April 9, 1969

Subject: Alternate Domestic Talc Sources
File No. 101

Dr. G. Hildick-Smith

Pete, we have to firm up the position the Company should have on the presence of the mineral Tremolite in talc. Your staff will have to do this for us since the objections to that mineral have been mainly medical or clinical as opposed to chemical or physical.

The reason we have to firm up our position is that we have moved into high gear on some alternate talc sources and it is normal to find different levels of Tremolite in many U.S. talcs. We are looking at some of those.

Historically, in our Company, Tremolite has been bad because it has needle type crystals. Our position has been that these can stand on end, penetrate the skin, and cause irritation; consequently, talcs exceeding trace contents have never been approved. Over the past year or two, the medical literature has made reference to potential hazards of talcs containing Tremolite and I have seen some articles under the umbra of environmental health agencies from here and abroad which pinpoint severe objections to that mineral in talcum powders.

Unfortunately, Tremolite has different varieties and can be easily confused with other members of the mineral class into which it falls. Chemically, it is mainly a calcium silicate with varying amounts of magnesium silicate and sometimes it carries iron with it in minor amounts. Some varieties of it match asbestos, and I gather there has been a lot of attention given to the hazards of inhaling minerals of that type lately.

EXHIBIT R

-2-

There is nothing we can do about the confused state of affairs on Tremolite from the mineralogical and chemical points of view as far as historic literature is concerned.

The question is...How bad is Tremolite medically, and how much of it can safely be in a talc base we might develop?

W.H.A.
W. H. Ashton

pm

cc: Dr. R. A. Fuller
Dr. E. R. L. Gaughran
Mr. R. J. Mortimer
Dr. T. H. Shelley
Dr. R. L. Sundberg

Exhibit S

CC:

Johnson & Johnson

New Brunswick, N. J.

April 15, 1969

Subject: ALTERNATE DOMESTIC TALC SOURCES

Project Code #101

Mr. W. H. Ashton:

Your inquiry of April 9th, 1969 addressed to Dr. G. Hildick-Smith has been referred to my attention for reply.

Over the years, I have reviewed the literature on the hazards relating to the inhalation of talc particles on several different occasions. In your memorandum, you indicate that Tremolite does have needle-type crystals and that our position has been that these could penetrate the skin and cause irritation. Actually, to the best of my knowledge, we have no factual information on this subject. It would seem logical that it could occur, although whether or not it would be of clinical significance would be conjectural.

We have been concerned to a much greater extent with regard to possible dangers relative to the inhalation of the talc with a spicule or needle-like crystalline structure as compared with the flat, platelet-type of crystalline structure. There are reports in the literature concerning talcosis which, as you know, is a form of pneumoconiosis attributed to the inhalation of talc. Reported studies have suggested that this does not occur in connection with the flat, platelet-type of talc, but does occur in connection with the spicule-type of crystalline structure characteristic of Tremolite. The reported instances have been extremely few but have, without exception, involved inhalations of high concentrations on an occupational basis of many years duration. Furthermore, we have occasionally received inquiries from various individuals, including General Johnson and several pediatricians, expressing concern over the possibility of the adverse effects on the lungs of babies or mothers who might inhale any substantial amounts of our talc formulations. In the past, we have replied to the effect that since our talc is essentially all of the platelet-type of crystalline structure, and is of a size which would not be likely to enter the pulmonary alveoli, we would not regard the usage of our powders as presenting any hazard. Obviously, if we do include Tremolite in more than unavoidable trace amounts, this sort of negation of such inquiries could no longer pertain.

EXHIBIT S

- 2 -

Mr. W. H. Ashton

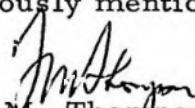
April 15th, 1969

Upon various occasions we have discussed the possibility of carrying out studies on animals which might provide factual information with regard to whether or not variable exposures to talc suspended in the environmental atmosphere might be productive of fibrotic and/or inflammatory reactions in lungs. For a variety of reasons, these have never been carried out here.

Since pulmonary diseases, including inflammatory, fibroplastic, and neoplastic types, appear to be on the increase, it would seem to be prudent to limit any possible content of Tremolite in our powder formulations to an absolute minimum. To the best of my knowledge, we have never been faced with any litigation involving either skin or lung penetration by our talc formulations. Some years ago, we were faced with a more or less serious problem resulting from what we consider to have been an unjust accusation of danger due to the presence of a small amount of boric acid in our talc. This created such a furor that we were more or less compelled to remove boric acid from the formulation. It is conceivable that a similar situation might eventually arise if it became known that our talc formulations contained any significant amount of Tremolite. Since the usage of these products is so widespread, and the existence of pulmonary disease is increasing, it is not inconceivable that we could become involved in litigation in which pulmonary fibrosis or other changes might be rightfully or wrongfully attributed to inhalation of our powder formulations.

It might be that someone in the Law Department should be consulted with regard to the defensibility of our position in the event that such a situation could ever arise.

It is my personal feeling that until we have at least substantial evidence, based on animal work, to the effect that the presence of Tremolite in our talc does not produce adverse effects, we should not extend its usage beyond an absolute minimum previously mentioned.


T. M. Thompson, M.D.

TMT:JAG

cc: Dr. R. A. Fuller
Dr. Gavin Hildick-Smith
Mr. W. J. Ryan
Dr. G. H. Lord
Dr. J. E. Willson
Dr. J. Bothwell

Exhibit T

Johnson & Johnson
BABY PRODUCTS COMPANY

April 4, 1974

SUBJECT: Notes on Visit to Denver Area
March 25 thru March 27, 1974

INFO

Mr. G. Lee

Mr. W.H. Ashton (Personal File)

3/25 - At Colorado School of Mines Research Institute with Dr. J. Krause and Dr. T. Mowatt.

Inspected and authorized assembly of high pressure assembly and following experiments.

1. Establish destruction of tremolite in presence of Vermont talc.
2. Establish destruction of chrysotile in presence of Vermont talc.
3. Determine whether or not fibrous structure is retained or destroyed in above.
4. Krause thinks chrysotile is destroyed with acid - will try experiment with and without high pressure.

The above to be run on low key up to point where we can file patent protection.

3/25 - At Colorado School of Mines with Professor Slaughter and above two CSMRI men.

Slaughter well aware of July 72 NIOSH report recently brought to our attention by Nashed/Rolle. Disappointing to hear that results of report on silica in powders was in Denver papers about ten days ago. No copy on hand.

Slaughter has visited NIOSH Hqts. in Cincinnati, at request of a John Crable. Crable in charge of all monitoring programs for NIOSH. Crable says NIOSH is to become the governing body for

PLAINTIFF'S
TRIAL EXHIBIT
2048

J&J-0070071

-2-

all other agencies concerned with exposure and inhalation hazards and told Slaughter that NIOSH has been given the money to go ahead. Crable says NIOSH will absorb MESA. (This would be disastrous since MESA has access to all U.S.B.M. information).

Slaughter has been teaching both MESA and NIOSH how to use their individually owned X-ray equipment for trace mineral assays. Slaughter finds NIOSH very ignorant of all phases of the mineral world involved in their assignments and because they realize that they have approached him to teach them how to set up for the task ahead.

The first monitoring program NIOSH will mount with emphasis is on talc according to Crable. In order of interest they will hit tremolite, chrysotile, quartz, opal, cristobalite.

I instructed Krause to get fully up on Slaughter's understanding of the agency relationships and rewrite the entire matter into a new proposal since the earlier were unclear.

Our earlier impression that Slaughter only needed \$4,000 was wrong since he also needs the input from the CSMRI to do the work and that is in the \$10,000 to \$15,000 area. Thus the total package is around \$20,000 not \$4,000.

3/26 - At CSMRI with Pattengill concerning proposal of March 13 and Professor Thomas of CSM.

Explained that we appreciate his proposal but that we are not engaged in researching chrysotile assay since we are not in the asbestos business. Thomas had not realized that and the matter is closed. (Slaughter will incorporate a similar idea to Thomas anyhow).

3/26 - Dinner with Caneer

Discussed uncomfortable aspects of possibility NIOSH might combine with MESA.

Caneer will check with Mining Congress friends to see if anything to rumor of merger. If true I will visit Goodwin directly.

J&J-0070072

-3-

3/26 - At Johns Manville Research Center

Bill Strieb and Sid Spiel in charge of Clay Mineral Research and Basis Research respectively. Dick Lamar called west on emergency and not present. Took Brause of CSMRI along.

Talc/Asbestos Methodology Matters

Spiel decided not to be represented officially on CTFM meetings which they previously requested. Will be glad to offer comments but JM does not want to be officially represented. Think that whole point has been missed from what they hear from others (I guess some committee members but not sure whom). JM thinks whole approach too sophisticated and beyond that ever intended by FDA. JM still prefers and improved optical backed up by X-ray as safest for customers and business also saving face for FDA at same time.

I gave Strieb proposals of talc/asbestos related to the joint effort idea since we are not really interested in that.

Silica Matters at JM

JM very active and very worried about recent upsurge in silica interest. JM law department has seen rough manuscript of criteria document NIOSH preparing on silica. They figure a firm criteria. document will destroy their diatome business (a silica skeleton of diatomites).

*in this in
join of kind
in mind?*

They know a bill was recently introduced into Congress to combine NIOSH with MESA but have no feel for it's future passing.

3/26 - At JM Canadian Mining Division

Gave Mike Sharratt samples of crushed ore and concentrate Russ made from their recent rocks sent to me from the Timmins ore body extensions which they staked out as JM claims. Sharratt will arrange some assays we do not do here. Told JM nothing about how Russ made concentrate or yield.

W.H. Ashton

paj

J&J-0070073

Exhibit U

February 13, 1973

105-4

JOHNSON'S Baby Powder
Review of Consumer Research

Mr. H. R. Callum

106-6

107-3

108-3

110-6

111-1

This document reviews past market research in an effort to isolate those product benefits and uses which are most important to consumers.

112-2

114-1

Conclusions:Teen and Female Market--

- 75% of teen girls and 80% of women use a talc. Therefore, the primary growth for JBP in this market will have to be taken from other brands (Avon, Cashmere Bouquet, etc).
- Teen girls and women rate fragrance and feel on skin as the most important qualities a talc should provide. JBP can make unique claims in this area as its fragrance is uniquely fresh and light and its feel is softer and more lubricious than that of other powders.
- Teen girls, women and men* all rate one benefit of talc very high: the ability to make them feel comfortable, clean, and dry. This benefit is particularly relevant in hot weather. JBP can fulfill this need uniquely as users perceive it to be more absorbent and more lubricious than other talcs.

* See Mr. Irvine's summary.

Baby Market--

85% of mothers using talc on their infants use JBP. Growth in this segment must come from both new talc users and conversion of users of other brands to JBP. Both users of other brands and non-talc users see JBP as a nice thing to do for baby but without practical benefits.

Possible Next Steps:

- Investigate in more depth the attitudes of teen, young women, and mothers who do not use talc or who use competitive brands.
- Investigate differences in consumer attitudes and usage patterns in different geographic regions.
- Attempt to substantiate claims of greater absorbency and greater lubricity of JBP over other baby and adult talc brands.
- Investigate the feasibility of a hot weather T.V. campaign built around the benefits of greater comfort, freshness and dryness

EXHIBIT U

INJ.000221062

- Examine the potential of an expanded print campaign to include teen and young women centered around JBP's fragrance and feel.
- Open a market test for female T.V. copy presenting JBP's fragrance and feel as main benefits.
- Develop additional baby copy which will present more definite product benefits to mother.

Summary of Findings:

1. Teenagers--

- Attitudes towards body powders -

Teens use powder as part of their bath routine, when they feel warm and sticky or simply to feel refreshed between showers. The two major benefits teens derive from talc usage are fragrance and feel on skin (softer, fresher, more comfortable). These benefits are not isolated from each other but form a whole state of "well being". Before applying the powder the girl is tired, warm and sticky, she does not feel clean or particularly pretty. After putting on talc she smells nice, feels cooler, softer and more feminine, her spirits are lifted.

- Specific Qualities of JBP -

JBPs strong points in the eyes of teenage users are:

- a) its fragrance which is light, natural, and can be worn in any situation without feeling overdressed.
- b) its image as a pure and mild product. Teens like "natural" products and are also very conscious of anything which might irritate their delicate skin.
- c) its increased smoothness and absorbency over other powders.

2. Women--

- Reasons why women use talcs -

Women use talc for fragrance and to feel dry and soft and refreshed. Once again the product benefits are not isolated but combine to contribute a general feeling of cleanliness, pleasantness and femininity.

- Specific qualities of JBP -

JBPs fragrance is pleasing yet discreet and does not clash with perfume. JBP is perceived as smoother in texture than other powders and more absorbent.

3. Baby Usage--

- Reasons why mothers use non-medicated powder -

Non-medicated baby powder is used as part of the bath routine and at diaper change. This pattern has remained constant over the past 6 years. Focus groups indicate present users of regular powder do not see it as very effective but use it for its emotional benefits--to make baby smell good, feel better and to feel as if they are doing something "extra" for their child. The two areas where current users appreciate the tangible benefits of talc are for its absorbency and to prevent baby's folds and creases from causing chafing.

Non-Users see talc as unnecessary for baby care, and possibly
harmful (clogs baby's pores, harmful if inhaled, etc.)

- Specific Qualities of JBP -

JBP's fragrance is preferred to that of other brands for
baby usage. JBP is seen as pure and reliable and very absorbent.

P. Wells

Patricia N. Wells

km

Attachments

Exhibit V

What you want
to know about
JOHNSON'S
Baby Powder.



EXHIBIT V

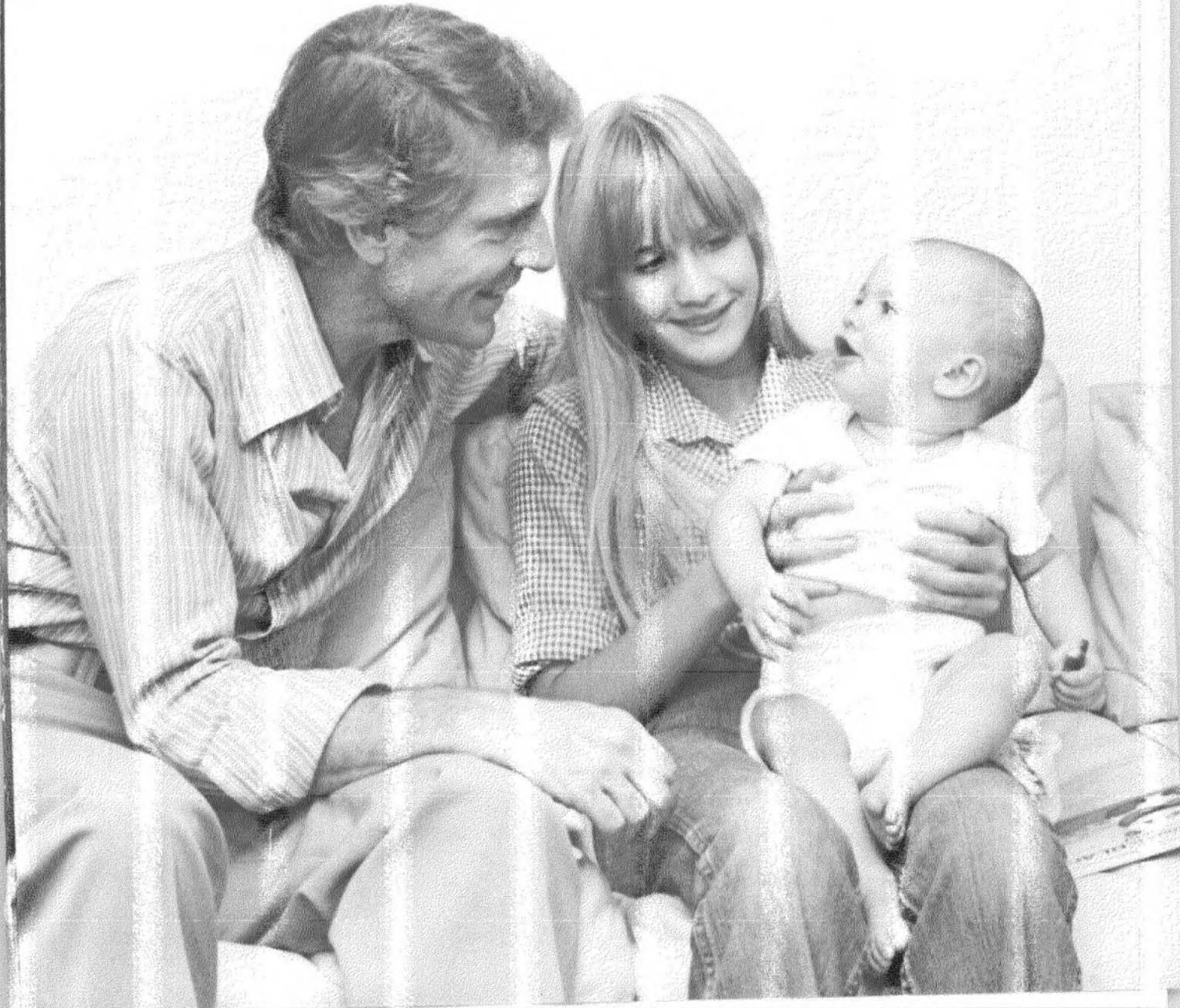
JNJ 000881819_0001

Prudencio Pltfs' Ex. 0698 pg 1

They want to know about products they use for themselves, their families, and...especially their babies.

More families are using JOHNSON'S Baby Powder than any other powder. So, more families are asking about JOHNSON'S Baby Powder.

Here are the questions asked most often, and the answers which come from over 75 years of experience.



About how it began

When did the idea of powdering baby start?

Women have always used some kind of powder to keep baby dry. Either rice flour, cornstarch, or adult talcum powder. Some ingenious New England mothers even collected powdered wood dust (which beetles made in wood floors) to use on baby's skin.

What was the first powder made just for babies?

In 1890, Johnson & Johnson developed a talcum powder especially designed for usage on a baby. It was then called a dusting powder.

When did JOHNSON'S Baby Powder originate?

In 1894, Fred B. Kilmer, the father of poet Joyce Kilmer, was in charge of the scientific laboratories at Johnson & Johnson. He decided that the maternity kit that was used by midwives and doctors needed a quality powder for new mothers and their babies. So, the new Johnson & Johnson powder was added to the kit. The following year, the name was changed to JOHNSON'S Baby Powder, and it was sold in pharmacies.

Has it ever changed?

Basically, no. Today, JOHNSON'S Baby Powder is practically the same as it was in 1890. No one has ever found a better way to make powder.

About what's in it

What ingredients are in JOHNSON'S Baby Powder?

The highest quality talc, and a light, fresh fragrance.

What is talc?

A soft, natural mineral that is mined from the earth.

Aren't all powders the same?

No. Because talcs are different. Johnson & Johnson owns its own talc mines in Vermont. These mines have an exceptionally high quality talc which is constantly checked to insure its safety and purity.

The talc has a minimum of impurities and a maximum of the platelet crystals that make talc smooth and adsorbent. You can feel the difference between other powders and the smoothness of JOHNSON'S Baby Powder.

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How is it so pure?

Johnson & Johnson is one of the few companies in the United States that owns its own talc mines. We, therefore, have complete control over the quality of our talc. We mine only that talc which is most free of foreign matter. Yet, even that is not good enough for us. Before we use it in our products, we put the talc through an extensive purification process. This process includes a cleansing procedure known as "flootation". It consists of many separate operations of "washing" the talc.

How is JOHNSON'S Baby Powder tested for purity and safety?

It is checked regularly for purity with sophisticated scientific equipment. The final product is tested on both animals and man to insure it does not cause adverse effects. This testing is continuously being upgraded as newer research techniques become available.

Is there asbestos in JOHNSON'S Baby Powder?

No. JOHNSON'S Baby Powder has been examined by the foremost experts in mineral analysis. Working in independent laboratories in the U. S. and in other parts of the world, the experts have confirmed the absence of asbestos fibers in JOHNSON'S Baby Powder. And the product is also monitored regularly to continuously assure us of its purity.

What gives it that "silky" feeling?

The platelets—or crystals—in the talc. These platelets slip, or glide, over each other. You might say they act as a dry lubricant. JOHNSON'S Baby Powder has a very high proportion of these platelets. That's why JOHNSON'S Baby Powder helps prevent friction. It keeps your skin feeling smooth and "silky". Helps eliminate clothing chafing and sticking.

What gives it that baby smell?

The special JOHNSON'S Baby Powder scent. This well-known fragrance has been identified as the "clean baby" smell for generations. It has been formulated and clinically tested to ensure its mildness.

About using it on baby

Why should I use JOHNSON'S Baby Powder on my baby?

Baby's world is a wet one. In the many folds and creases all over baby's body moisture can collect. Can irritate baby's

tender skin. JOHNSON'S Baby Powder adsorbs the moisture. Helps keep your baby feeling dry and comfortable. It helps prevent chafing by acting as a body lubricant. And the clean baby smell reminds you that your baby is loved.

How does powdering show my baby that I love him?

Your baby knows you love him by what he sees and hears... and by what he feels. Your touch says "love" to your baby. So, making him physically comfortable tells your baby you love him. Touching with JOHNSON'S Baby Powder not only says that you are there taking care of him, it creates a world of comfort in which baby can feel secure. Caring and comfort. They feel like love to baby.

How is mother's touch related to baby's growth and development?

Your touch not only says "love", it may actually help your baby grow and develop. Studies show that baby's growth and development depend upon physical stimulation, including your touch. So, simply stated, the more you touch and caress your baby, the better. Massaging with JOHNSON'S Baby Powder not only helps keep baby dry and comfortable, but it also helps make those important moments of touch a lot more enjoyable. For both of you.

When should I begin using powder on my baby?

As soon as he's born. Many hospitals do.

About teenagers using it

Is it true that many teenagers use JOHNSON'S Baby Powder?

Very much so. Over half the teenagers who sprinkle on powder use JOHNSON'S Baby Powder.

Why?

Teenagers put a lot of emphasis on their physical appearance and good grooming. Self-confidence is often tied to how a teenager feels about his or her appearance. JOHNSON'S Baby Powder keeps them feeling dry and comfortable. And, its unique scent is a gentle reminder that they're clean and fresh. Teenagers are proof that JOHNSON'S Baby Powder is a feeling you never outgrow.

Wouldn't an adult talc work better?

Teenagers go for what's natural.

Powders made especially for adults very often contain additives and heavy perfumes.

When should a teenager use it?

After a shower or bath, or just to freshen up. It's also a neat idea to pack it in your beach bag. Makes it easier to give sand the brush off. Sprinkle it in sports clothes and shoes and you'll help keep that nice, fresh smell. And you can have a soft, silky looking complexion in a shake by using JOHNSON'S Baby Powder as a translucent face powder.

Aren't they using it because it's around the house?

Many teenagers buy their own. And, many got the idea of using JOHNSON'S Baby Powder from friends who use it.

About adults using it

What can a baby powder do for grown ups?

Helps keep them dry and comfortable. What makes JOHNSON'S Baby Powder the best for baby makes it the best for adults, too.

But what about that "baby" fragrance?

Many women enjoy that fragrance as much on themselves as they do on their babies. Yet, should she wear perfume, a woman knows that the light scent won't interfere with her perfume.

Isn't it smarter to save money on a cheaper brand?

Cheaper brands do not have the same clean fragrance or high quality talc. They may even cake and clump when they get damp. Women who have tried them often wind up with a powder they use once or twice and then throw away. That's not a savings. On the other hand, buying JOHNSON'S Baby Powder which the whole family can use, will probably turn out to be the most economical thing to do.

Does it really work for men?

Since moisture and chafing can be a bigger problem for men, the drying and soothing feelings of JOHNSON'S Baby Powder can be a real relief. Comfort is a feeling even a man never outgrows.

Johnson & Johnson

**you never
outgrow**



Johnson & Johnson
BABY PRODUCTS COMPANY

BABY PRODUCTS COMPANY

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Baby Products Company.
New Brunswick, N.J. 08903

B-378 11/76

Exhibit W

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The FDA has tested Johnson's talc since the '70s. Every single time it did not contain asbestos. Learn more at factsabouttalc.com

Your questions deserve answers.



The talc in Johnson's Baby Powder is the purest, safest pharmaceutical-grade talc on earth. It doesn't contain asbestos and never will. We test every single lot to ensure it.

The FDA has tested Johnson's talc since the '70s and has confirmed - every single time - that it did not contain asbestos.

We have always cooperated fully and openly with the FDA and other regulators and have given them full access to our talc testing results.

We did not hide anything. Our openness and collaboration with the FDA and regulatory agencies is well-documented.

We have always acted with the utmost transparency in this matter. Nothing is more important to us than the health and safety of our customers. We've always been transparent, just like we've always been honest. If we had any reason to believe our talc was unsafe, it would be off our shelves immediately.

There is irrefutable scientific evidence that our talc is safe and beneficial to use. Go to factsabouttalc.com. There you'll find independent studies from leading universities, research from medical journals, and third-party opinions, so you can learn the facts and make up your own mind.



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63 Retweets 80 Quote Tweets 258 Likes

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Save your ad money for all the lawsuits coming your way oh and tell your other Pharmaceutical buddies who make opioids there screwed too. Nothing good ever comes from when all you can think about is making money.

 **Margaret May** @MamaBearRoars31 · Dec 19, 2018
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You hid what you knew and women died, children were exposed. Advertise somewhere that will buy your products again because that isn't me.

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You're guilty

 **Damian Ferry** @damian_ferry · Dec 19, 2018
Replying to @JNJNews
Somebody is being paid for this ad campaign. I can't imagine their run lasting much longer.

 **Kelly D #BlackLivesMatter** @be_loved_freak · Dec 20, 2018
Replying to @JNJNews
How many ounces of this is it safe for me to cram up my vag every day?

 **Lisa** @newsjunkie_2017 · Dec 20, 2018
Replying to @JNJNews
Before my mom passed away in 2016, she told me to stop using your products. I believe my mom.

 **Stephanie 😊** @honesteph · Dec 20, 2018
Replying to @JNJNews
Sounds like you hired a member of the Trump transition team to do damage control.

 **degilman** @degilman

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Trending with: #Cuties, #BoycottNetflix
4,170 Tweets

News · LIVE 
Wildfires continue to rage across the West Coast of the US

News · Trending 
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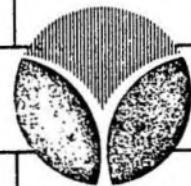
Messages 

EXHIBIT W

9/10/2020, 9:54 AM

Prudencio Plts' Ex. 4345 pg 1

Exhibit X



The Cosmetic, Toiletry and Fragrance Association, Inc.

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M I N U T E S

CTFA Task Force on Round Robin Testing of Consumer Talcum Products for Asbestiform Amphibole Minerals

A meeting of the above CTFA Task Force was held on May 17, 1977 at CTFA headquarters in Washington, D. C.. Those in attendance were:

RECEIVED

Murray Berdick, Chesebrough-Pond's
Regina Gallagher, Johnson & Johnson Research
R. W. Grexa, Cyprus Industrial Minerals
Ray Krammes, Whittaker, Clark & Daniels
George Lee, Johnson & Johnson Baby Products
Louis Murino, Cyprus Industrial Minerals
Herbert Ohlmeyer, Colgate-Palmolive
C. J. Parmentier, Cyprus Industrial Minerals
James Rodgers, The Mennen Company
George Sandland, Bristol-Myers Company
John Schelz, Johnson & JohnsonCHAIRMAN
Joseph Simko, Colgate-Palmolive
Ian Stewart, McCrone Associates
C. S. Thompson, R. T. Vanderbilt
J. J. Travérs, Avon Products, Inc.
Clifton Wilson, Food & Drug Administration
Ronald Yates, Food & Drug Administration
Norman Estrin, CTFA
Mort Westman, CTFA

JUN 20 1977

GEORGE LEE

Dr. Schelz opened the meeting by asking participants to introduce themselves and then stated the Task Force objectives as:

1. "Determine whether or not any 1976 production of major commercial talc products contain asbestiform amphibole contaminants.
2. Test and verify CTFA Method J4-1 for this purpose - assurance that method is accurate, reliable and practical!"

He then reported, these objectives have not yet been achieved.

EXHIBIT X

JNJ 000250604

Prudencio Pltfs' Ex. 0716 pg 1

Dr. Schelz summarized the results of the completed (first) round robin test, providing the following Table:

	Number of Laboratories Report (+)	Number of Laboratories Report (-)
CTFA Tremolite-Spiked Talc	1	6
Anthopyllite-Spiked Talc	7	0
Products		
#1	0	7
#2	0	7
#3	3	4
#4	0	7
#5	3	4
#6	0	7
#7	2	5

Note: Mt. Siani had not submitted results as of the meeting date (May 17, 1977)

With reference to discrepancies in results reported for products #3, #5, and #7, Dr. Schelz cited, as the principle source of problems, the optical microscopy and dispersion staining called for in Part II of the method (CTFA Method J4-1).

Dr. Schelz then proposed a round robin partial retest employing a TENTATIVE REVISION of Part II (CTFA Method J4-1) which incorporates suggestions from W. McCrone and other microscopists and in which instructions are more clear and precise. Copies of the TENTATIVE REVISION were distributed to those in attendance. As outlined by Dr. Schelz; sets of 4 coded samples, comprised of any random combination of the following:

- a) a standard prepared by "Spiking" talc with an amphibole mineral and
- b) the three products indicated by the first round robin test to provide inconsistent results (i.e., #3, 5 and 7 see Table above) would be distributed to participating labs in the new round robin test. All companies would be eligible to participate in this partial retest and the code would remain in Dr. Schelz's posession (as has the first-test code).

Dr. Schelz proposed that the OSHA Field Memorandum be retained as the working definition of fibrous asbestiform (emphasis placed on 5 length: 1 width provision) for the remainder of round robin testing. This proposal was put to a vote and approved and the Task Force agreed to initiate the round robin partial retest.

Drs. Estrin and Schelz urged that CTFA procedure be adhered to, and that only CTFA Standard Tremolite be used, in the retest. Dr. Schelz reminded the group that while discussion appears to be narrowing down to the 2 amphiboles, tremolite and anthopyllite, we are not attempting to identify these as such, but only as

amphiboles.. Dr. Schelz suggested that no attempt be made to prevent more than one participant from sending samples to the same outside testing lab because results could provide insight into that testing laboratory's intra-laboratory dependability.

After a brief discussion of the above, the Task Force, having no further business, adjourned.



Mort Westman
Director of Cosmetic Sciences

MW:er

June 13, 1977

Exhibit Y

T.M. NO. 7024 B

PAGE 1 of 5



STANDARD TEST METHOD

SUBJECT: ANALYSIS OF POWDERED TALC FOR ASBESTIFORM MINERALS BY TRANSMISSION ELECTRON MICROSCOPY

SUPERSEDES: ADL 1305 DATE: 3/8/89

AUTHORIZATION NO.: BCR 011362

1. SCOPE & PURPOSE

This method is applicable to the identification and quantitation of small (typically 1-20 micrometer) asbestos minerals in powdered talc. Samples may be previously screened with light microscopy or x-ray diffraction techniques.

2. PRINCIPLE OF METHOD

The combined techniques of transmission electron microscopy (TEM), selected area electron diffraction (SAED) and energy dispersive x-ray analysis (EDXRA) permit the detection of asbestos minerals based on morphological characteristics, followed by a definitive mineralogical identification of each fiber.

3. INTERFERENCES

Interferences are caused by fibrous particles which must be distinguished from positively identifiable asbestos, and by large particles or particle aggregates which may obscure fibers. Positively identified non-asbestos fibers include rolled talc, ribbon talc, antigorite, silica fibers and iron oxide fibers. Organic additives such as perfumes may crystallize out as fibers or needle-shaped crystals in finished cosmetic products. In the absence of positive identification, all other fibers must be classified as unidentifiable.

4. INSTRUMENTAL CONDITIONS

The talc specimen grids are examined in the TEM at an accelerating voltage of 120 kv and at magnification of 20,000X and 5,000X.

5. SENSITIVITY

This method is capable of detecting a single fiber as small as 1 micrometer (μm) long by 0.075 μm wide in the entire TEM field, which results in a theoretical detection limit of 10^{-5} weight percent. Such fibers usually can be identified readily by SAED and EDXRA. The mass of a fiber with the above dimensions is 1.1×10^{-14} g for chrysotile and 1.5×10^{-14} g for amphibole.

EXHIBIT Y

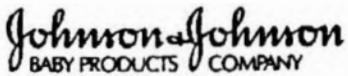
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JNJ 000291563

Prudencio Pltfs' Ex. 0811 pg 1

T.M. NO. 7024

PAGE 2 of 5



STANDARD TEST METHOD

SUBJECT: ANALYSIS OF POWDERED TALC FOR ASBESTIFORM MINERALS BY TRANSMISSION ELECTRON MICROSCOPY

SUPERSEDES: ADL 1305 DATE: 3/8/89

AUTHORIZATION NO.: BCR 011362

6. LIMIT OF QUANTIFIABLE DETECTION

The detection of five or more asbestos minerals of one variety in an analysis constitutes a quantifiable level of detection. When no asbestos minerals are detected, a representative fiber size is used to calculate a detection limit. A representative fiber size is 3 μm long by 0.2 μm wide by 0.06 μm thick, which is considerably larger than the smallest fiber that can be detected (see section 5, SENSITIVITY), but is more typical of small asbestos fibers that are detected in talc analyses. The mass of five such fibers is calculated as follows:

$$\begin{aligned} 3 \mu\text{m} \times 0.2 \mu\text{m} \times 0.06 \mu\text{m} &= 0.036 \mu\text{m}^3 \text{ per fiber} \\ x 3.3 \times 10^{-12} \text{ g} / \mu\text{m}^3 &= 1.2 \times 10^{-13} \text{ g per fiber} \\ x 5 \text{ fibers} &= 6 \times 10^{-13} \text{ grams per 5 fibers.} \end{aligned}$$

The limit of quantifiable detection for most talc analyses is approximately 6×10^{-4} weight percent. The theoretical and quantifiable detection limits assume homogeneity of the material being sampled.

QUALITY ASSURANCE

Blank suspensions are routinely prepared and tested in order to monitor potential residual contamination from the sample jars. Blank carbon-coated grids are routinely tested to monitor the ambient fiber count. If greater than 4 fibers per grid are present, the jars are pre-cleaned or new carbon-coated grids are prepared, respective of the test.

8. BACKGROUND CORRECTION

As of the time of this writing, background correction has not been necessary. The amount of background asbestos detected has been insignificant in comparison to the levels of asbestos found in contaminated samples.

9. PREPARATION AND ANALYSIS TIME

Preparation time per sample (including preparation of related materials) is one hour. Analysis search time per sample is a maximum of two hours.

10. APPARATUS

- A. Analytical balance with 0.0001 gram sensitivity
- B. Weighing boats
- C. Narrow spatula

T.M. NO. 7024

PAGE 3 of 5



STANDARD TEST METHOD

SUBJECT: ANALYSIS OF POWDERED TALC FOR ASBESTIFORM MINERALS BY TRANSMISSION ELECTRON MICROSCOPY

SUPERSEDES: ADL 1305 DATE: 3/8/89 AUTHORIZATION NO.: BCR 011362

- D. Wide mouth polyethylene jars (125 ml)
- E. Mild ultrasonic bath, minimum 50 watts
- F. Micropipettor (5-10 μ l range) with disposable tips
- G. Standard 3 mm diameter, 200 mesh, copper TEM grids, covered with a carbon-coated formvar film.
- H. Transmission electron microscope (TEM) with an 80-120 kv accelerating voltage and energy dispersive x-ray analyzer.

11. REAGENTS

- A. Methyl cellulose, powder, USP 4000 cps - Fisher Certified Reagent #M-352 or equivalent
- B. Water: deionized, particle free (<0.2 μ m filtered)
- C. Methyl cellulose solution: 0.002% (wt/vl) (20 ppm). Dissolve 20 \pm 0.5 mg of methyl cellulose in 500 ml of deionized particle free water to make a 0.004% stock solution. Dilute 1:1 to make a working solution.

NOTE: Methyl cellulose acts as a wetting agent to aid in maintaining a uniform particle distribution as the sample dries, by greatly reducing the surface tension of water.

12. SAMPLE PREPARATION

- 12.1. Transfer 30 to 50 mg of talc powder to a clean 125 ml polyethylene jar.
- 12.2. Add 80 ml of 20 ppm methyl cellulose solution, cap and shake vigorously for one minute.
- 12.3. After shaking, loosen cap and ultrasonicate for 10 minutes in order to disperse the finer particles. Then shake again for one minute to produce a uniform suspension.
- 12.4. Immediately after shaking, uncap and remove 9.2 microliters with a micropipette.



T.M. NO. 7024

PAGE 4 of 5

STANDARD TEST METHOD

SUBJECT: ANALYSIS OF POWDERED TALC FOR ASBESTIFORM MINERALS BY TRANSMISSION ELECTRON MICROSCOPY

SUPERSEDES: ADL 1305 DATE: 3/8/89 AUTHORIZATION NO.: BCR 011362

12.5. Transfer a 9 μ l drop to a carbon film covered TEM grid. (Grid was first lightly anchored by 2 parallel strips of double-stick tape mounted 3 mm apart on a clean glass microscope slide.) Repeat to make two sample grids per talc sample.

NOTE: Do not expel the remaining 0.2 μ l suspension from the micropipette tip. It tends to sputter and frequently destroys the stability of the sample drop.

12.6 Transfer slide with grids to a desiccator. (Drying time is 2-3 hours.) Do not leave the grids on the slide for more than one day as the double-stick tape may adhere too tightly.

NOTE: The talc:water ratio may need to be varied for some samples. Preparation of talc samples with a significantly finer or coarser particle size results in large differences in particle coverage on the TEM grid.

TEM ANALYSIS

13.1 Definition of fiber: An elongated particle with parallel sides and an aspect ratio $\geq 3:1$. The definition employed may vary with the needs of the client.

13.2 Scan sample at 120-150X magnification to check for even dispersion of particles and to locate grid squares with optimum particle density. (Optimum particle density is particle coverage over 15-35% of the field of view.)

13.3. Scan three grid squares on each grid at 20,000X magnification and seven grid squares on each grid at 5,000X for asbestos minerals. Each asbestos mineral is recorded as to type (chrysotile, tremolite, anthophyllite, etc.), structure (bundle, clump, fiber) and dimensions (length x width).

13.4. Questionable fibers are examined first by SAED. The chrysotile SAED pattern is unique and diagnostic. Amphibole SAED patterns are variable but usually characteristic. Additional analysis and measurement of amphibole SAED patterns are done if warranted.

13.5. Ten percent of chrysotile fibers are checked by EDXRA for further confirmation. If the SAED pattern is not clearly diagnostic, or if it is consistent with an amphibole SAED pattern, then it is examined by EDXRA to confirm the identification or to identify the type of amphibole.

T.M. NO. 7024

PAGE 5 of 5



STANDARD TEST METHOD

SUBJECT: ANALYSIS OF POWDERED TALC FOR ASBESTIFORM MINERALS BY TRANSMISSION ELECTRON MICROSCOPY

SUPERSEDES: ADL 1305 DATE: 3/8/89 AUTHORIZATION NO.: BCR 011362

14. CALCULATION OF RESULTS

14.1.A. Mass of chrysotile fibers: $M(f)$

$$M(f) = \pi r^2 l \times d$$

$\pi = 3.14159$

$r = \text{fiber radius}$

$l = \text{fiber length}$

$d = \text{density of chrysotile} = 2.55 \times 10^{-12} \text{ g}/\mu\text{m}^3$

14.1.B. Mass of asbestosiform amphibole particles: $M(a)$

$$M(a) = l \times w \times th \times d$$

$l = \text{length}$

$w = \text{width}$

$th = \text{thickness} \approx 0.3 \text{ width (approximation)}$

$d = \text{density of amphiboles} = 3.3 \times 10^{-13} \text{ g}/\mu\text{m}^3$

14.2.A. Mass of talc deposited on each TEM grid: $M(s)$

$$M(s) = T \times (V/H)$$

$T = \text{amount of talc sampled (step 12.1)}$

$V = \text{volume of aliquot transferred to TEM grid (step 12.5)}$

$H = \text{volume of methyl cellulose solution (step 12.2)}$

14.2.B. Total estimated talc mass examined: $M(t)$

$$M(t) = M(s) \times (N \times A(s))/A(g)$$

$N = \text{number of grid squares examined}$

$A(s) = \text{area of a single TEM grid square}$

$A(g) = \text{area of an entire TEM grid (effective area over which a 9 microliter drop of suspension dries)}$

14.3. Weight percent:

$$\frac{\text{sum total of } M(f) \text{ or } M(a) \times 100}{M(t)}$$

15. CALCULATION OF A DETECTION LIMIT

15.1. $M(d1) = \text{A minimum quantifiable mass of asbestos fibers, based on the detection of 5 fibers (approximately } 6 \times 10^{-13} \text{ grams, from Section 6).}$

15.2. Detection Limit (Weight Percent) = $\frac{M(d1) \times 100}{M(t)}$

Exhibit Z



Name: Anthony Michael Hernandez-Valdez | **DOB:** 9/23/1998 | **MRN:** 36945558 | **PCP:** Christine Emma Viney, PA

Fusion-Stamp Ngs Panel, Non-Blood - Details

Study Result

Narrative

Molecular diagnostic test results should be interpreted in the context of standard clinical, laboratory and pathological findings. Molecular genetic test results impart a probabilistic risk of disease. In order to derive the most meaningful benefit from this testing, it is recommended that the results and subsequent options from these complex tests be discussed with patients by a trained medical/genetics professional.

False negative results may be due to sampling error or errors in sample handling, as well as clonal/signal density below the level of detection. Genotyping errors can result from trace contamination of PCR reactions and from rare genetic variants that interfere with analysis, including deletions or polymorphisms in primer binding sites which prevent allele amplification.

This test was developed and its performance characteristics determined by Stanford Clinical Laboratories. It has not been cleared or approved by the U.S. Food and Drug Administration.

The FDA has determined that such clearance or approval is not necessary. This test is used for clinical purposes. It should not be regarded as investigational or for research. This laboratory is certified under the Clinical Laboratory Improvement Amendments of 1988 ('CLIA') as qualified to perform high complexity clinical laboratory testing.

Component	Your Value	Standard Range
Clinical Indication	Your Value Fusion gene detection in solid tumors for diagnosis, prognosis, and treatment selection	
Surgical Pathology Case #	Your Value SHS-22-03759 A2 (22MS-0133 1B)	
% Tumor	Your Value 30 %	Standard Range %
Result, Non-blood	Your Value Negative: No fusions detected	
Method	Your Value The Stanford Actionable Mutation Panel for Fusions (Fusion-STAMP) is a targeted next generation sequencing method that detects potentially clinically actionable gene fusion events in cancer. The targeted sequencing approach and integrated bioinformatics workflow is optimized for sequencing of formalin fixed paraffin embedded tissue specimens. The workflow includes isolation of total RNA molecules, followed by efficient preparation of sequencing libraries and a target enrichment approach to capture mRNA transcript regions of interest for sequencing. The enrichment is done using custom designed libraries of capture oligonucleotides that target a specific set of expressed genomic regions. This panel fully targets the transcript isoforms of 43 genes which were selected based on their known impact as actionable targets of existing and emerging anti-cancer therapies, their prognostic features, and/or their utility as diagnostic cancer biomarkers. Pooled libraries are sequenced on an Illumina sequencing instrument. Genes tested by NGS: ALK, ATF1, BCOR, BRAF, CAMTA1, CCNB3, CIC, COL1A1, DDIS3, EGFR, ERG, ETV6, EWSR1, FGFR1, FGFR2, FGFR3, FLI1, FOXO1, FUS, HMGA2, MET, MYB, NAB2, NCOA2, NRG1, NTRK1, NTRK2, NTRK3, PAX3, PAX7, PDGFB, PHF1, PPARG, RAF1, RET, ROS1, SS18, SSX1, STAT6, TFE3, USP6, WT1, YWHAE	

Interpreted By Your Value J. Zehnder, MD

General Information

Ordered by Mohana Roy

Collected on 03/15/2022 11:39 AM from Other (Tissue)

Resulted on 04/04/2022 2:57 PM

Result Status: Final result

EXHIBIT Z